510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K123517

Date of Summary : September 30, 2013.

1. SUBMITTER'S IDENTIFICATION:

SD Biosensor, Inc.

Address

C-4th&5th Floor Digital Empire Building 980-3, Yeongtong-dong

Yeongtong-gu Suwon-si, Kyonggi-do Korea, 443-813

TEL: 82-31-300-0418

FAX: 82-31-300-0497

Contact Person

Ms. Anis Kim

QA/RA Assistant manager

2. DEVICE NAME:

Proprietary Name	: SD GlucoMentor™
Common Name	: Blood Glucose Monitoring System
Regulation Number	: 21 CFR §862.1345
Classification Name	: Blood Glucose Test System, Over the Counter
Product Code	: NBW
Subsequent Product Code	: CGA / JJX
Regulatory Class	: II

3. PREDICATE DEVICES:

	Predicate Device
(510(k) Number)	K100398
(Device Name)	SmartLink™ Gold

4. DEVICE DESCRIPTION:

SD GlucoMentor™ blood glucose system is an Rx/OTC blood glucose monitoring system to be used

by professional healthcare personnel or diabetics at home to measure the glucose concentration for aiding diabetes management.

SD GlucoMentor™ blood glucose monitoring system is comprised of the following.

- SD GlucoMentor™ blood glucose meter
- SD GlucoMentor™ blood glucose test strip
- SD Glucose control solution
- SD Glucose check strip

A drop of blood sample from the finger prick works with glucose oxidase and the mediators in the test strip to make a small electric current proportional to the glucose concentration in the blood. The meter reads the current and displays the blood glucose result equivalent to the current.

The system is a battery-operated portable device and stores 500 test results in memory. The user can search the stored results with three presentations of 7, 14 and 30-day averages of test results stored in memory: normal, pre-meal and post-meal state averages. The system can set the beep, hypo warning, date, time, post-meal alarm and alarm. The system can also set the pre-meal and post-meal mark. Test results are displayed with mg/dL unit. A check strip allows the meter to check a problem and the control solution allows the meter and test strip to be checked.

5. INDICATION FOR USE:

The SD GlucoMentor Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, or palm. The SD GlucoMentor Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

The SD GlucoMentor Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The SD GlucoMentor Test Strips are for use with the SD GlucoMentor Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, or palm.

The SD GlucoMentor multi Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, upper arm, or forearm. The SD GlucoMentor multi Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient

use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with auto-disabling, single-use lancing devices.
The SD GlucoMentor multi Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).
The SD GlucoMentor multi Blood Glucose Test Strips are for use with the SD GlucoMentor multi Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, or palm.

6. COMPARISION TO PREDICATE DEVICE:

The SD GlucoMentor™ blood glucose monitoring system of SD Biosensor, Inc. is substantially equivalent to our SD SmartLink™ GOLD Glucose Monitoring System, K100398. Both the subject and predicate devices are similar in intended use and basic fundamental scientific technology with differences in:

A. SD GlucoMentor™ Meter
Appearance, Size, Weight, Color, Codechip, PCB, LCD

B. SD GlucoMentor™ Test strip
Printed Film, Size

7. DISCUSSION OF NON-CLINICAL TESTS PERFORMED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE ARE AS FOLLOWS:

Based on our risk analysis evaluation results, and, in accordance with the FDA "Draft Guidance for Industry and FDA Staff – Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems, 10/24/06", outlined performance characteristics, the following testing was conducted to support the modifications found in our subject device:

- Software Verification and Validation Testing
- Precision Evaluation
- Linearity Testing
- Performance Evaluation
- Equipment Temperature & Humidity Exposure Test
- Mechanical Resistance to Vibration-Environmental Testing
- Document TD-8 Testing Temperature Study
- Electromagnetic Compatibility Study (ISO 15197:2003)
- Electrical Safety Study (IEC 61010-1 & IEC 61010-2)

None of the testing demonstrated any design characteristics that violated the requirements of the FDA recognized standards or resulted in any safety hazards. It was our conclusion that testing met all relevant standards requirements.

8. DISCUSSION OF CLINICAL TESTS PERFORMED:

Clinical sensitivity and clinical specificity testing is not applicable.

A system accuracy evaluation (Method Comparison with Predicate Device) for the SD GlucoLink Blood Glucose Monitoring System was performed according to ISO 15197:2003.

A user performance study was performed to demonstrate that lay consumers could obtain accurate results using the SD GlucoLink Blood Glucose Monitoring System. The study was performed using capillary whole blood from fingertip, palm, forearm, and upper arm sample sites.

9. CONCLUSION:

Based on documentation supplied with this submission, conclusions drawn from clinical and bench testing of the subject device demonstrates that the subject
The SD GlucoMentor™ blood glucose monitoring system is substantially equivalent to predicated our legally marketed predicate device, Smartlink GOLD (K100398).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 6, 2014

SD BIOSENSOR
JIGAR SHAH
JIGAR MDI CONSULTANTS
55 NORTHERN BLVD
GREAT NECK NY 11021

Re: K123517
Trade/Device Name: GlucoMentor Blood Glucose Monitoring System,
GlucoMentor Multi Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: January 10, 2014
Received: January 13, 2014

Dear Mr. Shah:

This letter corrects our substantially equivalent letter of January 17, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K123517

Device Name SD GlucoMentor™ multi blood glucose monitoring system

INDICATIONS FOR USE

The SD GlucoMentor multi Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, upper arm, or forearm. The SD GlucoMentor multi Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with auto-disabling, single-use lancing devices.

The SD GlucoMentor multi Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The SD GlucoMentor multi Blood Glucose Test Strips are for use with the SD GlucoMentor multi Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, or palm.

Prescription Use X		Over-The-Counter Use X
(Part 21 CFR 801 Subpart D)	AND/OR	(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD)

Katherine Serrano-S
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Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k123517